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NOTICE OF ALLOWANCE AND FEE(S) DUE

23416

7590

03/27/2009

CONNOLLY BOVE LODGE & HUTZ, LLP
P O BOX 2207
WILMINGTON, DE 19899

EXAMINER

OLSON, ERIC

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 03/27/2009

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,424	07/22/2005	Klaus Henning	09600-00028-US	6261

TITLE OF INVENTION: HIGHLY BRANCHED, UNSUBSTITUTED OR LOW-SUBSTITUTED STARCH PRODUCTS, DIALYSIS SOLUTION AND PLASMA EXPANDER CONTAINING THE SAME, AND THE USE THEREOF

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	06/29/2009

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. **PROSECUTION ON THE MERITS IS CLOSED.** THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN **THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE** OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. **THIS STATUTORY PERIOD CANNOT BE EXTENDED.** SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: **Mail** **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax **(571)-273-2885**

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

23416 7590 03/27/2009

CONNOLLY BOVE LODGE & HUTZ, LLP
P O BOX 2207
WILMINGTON, DE 19899

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Klaus Henning

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APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	06/29/2009

EXAMINER	ART UNIT	CLASS-SUBCLASS
OLSON, ERIC	1623	514-060000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a **Customer Number is required.**

2. For printing on the patent front page, list

- (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, 1 _____
- (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2 _____
- 3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
- ☐ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 167 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 167 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability**Application No.**

10/524,424

Examiner

ERIC S. OLSON

Applicant(s)

HENNING, KLAUS

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Applicant's amendment submitted December 2, 2008.
2. ☒ The allowed claim(s) is/are 1 and 15-34.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of the:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date 2/14/2007
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

/Eric S Olson/
Examiner, Art Unit 1623

/Shaojia Anna Jiang/
Supervisory Patent Examiner, Art Unit 1623

Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Eamonn Morrison on February 27, 2009.

Claim 1 is amended as follows:

1. (Currently Amended) A modified hydroxyethyl- or hydroxypropyl- substituted starch product for clinical use, wherein said hydroxyethyl- or hydroxypropyl- substituted starch product has a degree of branching in the range of from 8 to ~~20~~ 10 mol %, a degree of substitution MS of up to 0.3, an average molecular weight (M_w) in the range of from 10000 to 450000, with the proviso that said hydroxyethyl- or hydroxypropyl- substituted starch product is not derived from an amylopectin fraction.

Claim 14 is cancelled.

Claims 15 and 17-26 are amended as follows:

15. (Currently Amended) The modified hydroxyethyl- or hydroxypropyl-substituted starch product of claim 44 1, wherein said modified hydroxyethyl- or hydroxypropyl-

substituted starch product has a degree of substitution MS in the range of from 0.05 to 0.3.

16. (Previously Presented) The modified hydroxyethyl- or hydroxypropyl-substituted starch product of claim 15, wherein said modified hydroxyethyl- or hydroxypropyl-substituted starch product has a degree of substitution MS in the range of from 0.05 to 0.15.

17. (Currently Amended) The modified hydroxyethyl- or hydroxypropyl-substituted starch product of claim 44 1, wherein said modified hydroxyethyl- or hydroxypropyl-substituted starch product has an average molecular weight (M_w) in the range from 10,000 to 40,000.

18. (Currently Amended) The modified hydroxyethyl- or hydroxypropyl-substituted starch product of claim 44 1, wherein said modified hydroxyethyl- or hydroxypropyl-substituted starch product has an average molecular weight (M_w) in the range from 40~000 to 450,000.

19. (Currently Amended) The modified hydroxyethyl- or hydroxypropyl-substituted starch product of claim 44 1, wherein the C2/C6 ratio of said modified hydroxyethyl- or hydroxypropyl-substituted starch product is in the range of from 4 to 20.

20. (Currently Amended) The modified hydroxyethyl- or hydroxypropyl-substituted starch product of claim 19, wherein said C2/C6 ratio is in the range of from 5 to 9.
21. (Currently Amended) The modified hydroxyethyl- or hydroxypropyl-substituted starch product of claim 44 1, wherein said hydroxyethyl- or hydroxypropyl-substituted starch product is hydroxyethylated starch.
22. (Currently Amended) The modified hydroxyethyl- or hydroxypropyl-substituted starch product of claim 44 1, wherein the reducing ends of said modified hydroxyethyl- or hydroxypropyl-substituted starch product are inactivated by oxidation or reduction.
23. (Currently Amended) A dialysis solution comprising water and the modified hydroxyethyl- or hydroxypropyl-substituted starch product of claim 44 1.
24. (Currently Amended) A plasma expander comprising water and the modified hydroxyethyl- or, hydroxypropyl-substituted starch product of claim 44 1.
25. (Currently Amended) A method of peritoneal dialysis comprising dialyzing with a dialysis solution comprising the modified hydroxyethyl- or hydroxypropyl-substituted starch product of claim 44 1 as colloid osmotic agent in dialysis.
26. (Currently Amended) A method for volume replacement comprising administering

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to a patient in need thereof a plasma expander comprising the modified hydroxyethyl- or hydroxypropyl-substituted starch product of claim 44 1.

Abstract

The Abstract is amended as follows:

~~—Highly branched, unsubstituted or low-substituted starch products, dialysis solution and plasma expander containing the same, and the use thereof~~

Known hydroxyethylated and -propylated starch types for use as colloid osmotic agent in peritoneal dialysis or as volume replacement composition (plasma expander) have the disadvantage that complete degradation by amylase is not possible owing to the more or less extensive substitution by hydroxyethyl or hydroxypropyl groups. As a consequence thereof, residual fragments remain in the body and are eliminated only very slowly or are stored in various organs/tissues, especially with relatively high and/or long-term dosage. These disadvantageous properties can be very substantially avoided according to the invention with a highly branched, unsubstituted or low-substituted starch product, i.e. with a starch which has a significantly higher degree of branching than amylopectin, and has the degree of α -1,6 branching of glycogen, or exceeds the latter and - if substituted - has a degree of substitution MS of only up to 0.3.

Detailed Action

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 2, 2008 has been entered.

This office action is a response to applicant's communication submitted December 2, 2008 wherein claim 1 is amended, claims 2 and 4-13 are cancelled, and new claims 14-34 are introduced. This application is a national stage application of PCT/EP03/08411, filed July 30, 2003, which claims priority to foreign application DE10237442.2, filed August 16, 2002.

Claims 1 and 15-34 are pending in this application.

Claims 1 and 15-34 as amended are examined on the merits herein.

Reasons for Allowance

Applicant's amendment, submitted December 2, 2008, and the accompanying examiner's amendment, with respect to the rejection of instant claims 1, 2, 5-8, 11, and 13 under 35 USC 103(a) for being obvious over Sommermeyer et al. in view of Antrim, has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to recite only subject matter which is shown to produce unexpected results. Therefore the rejection is withdrawn.

Applicant's amendment, submitted December 2, 2008, and the accompanying examiner's amendment, with respect to the rejection of instant claims 1, 2, 4, 6-8, 10, and 12 under 35 USC 103(a) for being obvious over Sommermeyer et al. '140 in view of Antrim, has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to recite only subject matter which is shown to produce unexpected results. Therefore the rejection is withdrawn.

Applicant's amendment, submitted December 2, 2008, and the accompanying examiner's amendment, with respect to the rejection of instant claim 9 under 35 USC 103(a) for being obvious over Sommermeyer et al. in view of Antrim in view of Naggi et al., has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to recite only subject matter which is shown to produce unexpected results. Therefore the rejection is withdrawn.

Applicant's amendment, submitted December 2, 2008, and the accompanying examiner's amendment, with respect to the rejection of instant claim 9 under 35 USC 103(a) for being obvious over Sommermeyer et al. '140 in view of Antrim in view of Naggi et al., has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to recite only subject matter which is shown to produce unexpected results. Therefore the rejection is withdrawn.

Currently claims 1 and 15-34 are pending in this application and have been examined on the merits herein. Applicant's amendment submitted December 2, 2008, and the accompanying examiner's amendment, are seen to be persuasive to remove all rejections of record in the previous office action and place the application in condition for allowance. Reasons for allowance are as follows:

The claimed subject matter is seen to be adequately described and enabled by the specification as originally filed. For example pp. 5-7 of the specification as originally filed disclose highly branched starches having the claimed properties. Pp. 8-10 of the specification describe using these starches for peritoneal dialysis and as plasma expanders. Pp. 10-12 disclose that these starches are tolerated in rats with reduced tissue storage compared to prior art starch products after repeated daily infusion. One skilled in the art would have realized from this disclosure that these starches can be administered safely in peritoneal dialysis or volume replacement compositions in place of the prior art starches. Therefore one skilled in the art would have been enabled to make and use the starches for this purpose. For these reasons the claims meet the requirements of 35 USC 112.

Furthermore the claims are novel and non-obvious over the prior art. With regard to the substituted starches of claims 1 and 15-26, the prior art does not teach substituted starches with such a high degree of branching. Prior art starches such as those of Sommermeyer et al. typically have a degree of branching of about 5%. While Antrim does disclose a motivation for increasing the degree of branching of prior art starches in order to reduce their retrogradation, The previously submitted declaration of

Dr. Klaus Henning discloses that hydroxyethylated starches having a degree of branching of 8-10% have an unexpectedly low storage effect when administered to a subject. This effect is not disclosed by Antrim or any other prior art. Therefore the declaration is persuasive to overcome the *prima facie* case of obviousness made over Sommermeyer in view of Antrim, and render the claims non-obvious.

As regards the unsubstituted starches of claims 27-34, these starches have a combination of molecular weight and degree of branching that is not seen in the prior art. The only prior art starches having such a high (11-20%) degree of branching are glycogens, which have a much higher molecular weight than that recited in the claims. One of ordinary skill in the art would have no motivation to either increase the degree of branching of ordinary unsubstituted starches (e.g. amylopectin) or reduce the molecular weight of glycogen to arrive at the claimed invention. Furthermore one of ordinary skill in the art would certainly have had no motivation to use glycogen in a dialysis solution or plasma expander in the methods of claims 33-34.

Therefore the claimed invention meets the requirements of 35 USC 102 and 103.

Accordingly, Applicant's amendment submitted December 2, 2008, and the accompanying examiner's amendment, are sufficient to remove all rejections made in the prior office action as discussed above and to place the application in condition for allowance.

Any comments considered necessary by Applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably

accompany the issue fee. Such submissions should be clearly labeled, "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shaojia Anna Jiang/
Supervisory Patent Examiner, Art Unit 1623